



Patent
Docket No: 151P11200US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Moskowitz

Group Art Unit: 3739

Serial No.: 10/699,586

Filed: October 31, 2003

Examiner: Rollins, Rosiland Stacie

For: APPARATUS AND METHOD FOR MAKING A HOLE IN THE DURA

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

February 22, 2006

Date

Signature

BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This is an appeal from the Office Action mailed on May 3, 2005 finally rejecting claims 1 – 15. A Notice of Appeal was filed by facsimile on November 3, 2005. Accordingly, the due date for the Brief on Appeal, having been extended two (2) months, is March 3, 2006.

The fee required under 37 CFR §1.17(c) for the appeal should be charged to Deposit Account No. 13-3723.

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

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REAL PARTY IN INTEREST

The real party in interest is Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, Minnesota 55432-5604, as evidenced by the Assignment recorded on February 24, 2004 at Reel 014410, Frame 0574.

RELATED APPEALS AND INTERFERENCES

Appellant, Appellant's legal representative and the assignee are not aware of any appeals or interference proceedings before the U.S. Patent and Trademark Office that will directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 1 and 6 – 9 and 13 – 15 are pending in this application.

Claims 2 – 5 and 10 – 12 have been canceled.

Claims 1 and 6 – 8 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 6,761,718, Madsen et al (“Madsen et al ‘718”), in an Office Action made final mailed May 3, 2005.

Claims 9 and 13 – 15 have been indicated as being allowable if submitted in a separate, timely filed amendment canceling the non-allowable claims in the Advisory Action mailed July 22, 2005.

STATUS OF AMENDMENTS

All amendments have been entered. No amendments are pending.

SUMMARY OF CLAIMED SUBJECT MATTER

The apparatus and methods of the present invention are used during shunt surgery to create a hole of a predetermined diameter in the dura of the brain. The apparatus and methods control leakage of cerebrospinal fluid (CSF) around a catheter placed through the dura in order to accomplish shunting into the ventricles into the sagittal sinus. Controlling leakage of CSF can improve shunt performance by controlling or eliminating the potential for the serious side effects discussed above. In order to control leakage of CSF, a smooth, round hole of a very precise diameter is made in the dura.

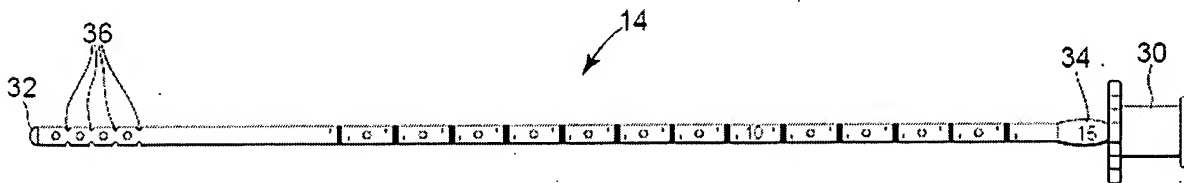
There are two independent claims under consideration, namely claim 1 and claim 9.

Claim 1

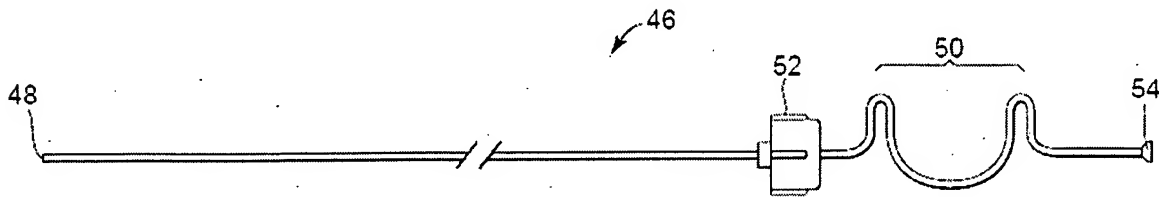
Claim 1 recites an apparatus for making a hole in the dura of a patient for the insertion of a catheter. The hole in the dura has a first predetermined diameter. The catheter has a second predetermined diameter.

The apparatus comprises a catheter with a lumen having a first predetermined diameter and a stylet having a first end adapted for insertion into the lumen of the catheter. A second end of the stylet is formed with a tip having a diameter having a diameter approximately equal to the diameter of the hole in the dura (the first predetermined diameter). The diameter of the hole in the hole is not greater than diameter of tip of the stylet. The apparatus also comprises means for applying an electrical current to the tip of the stylet to cauterize the dura.

A preferred embodiment of the catheter (14) is illustrated below.



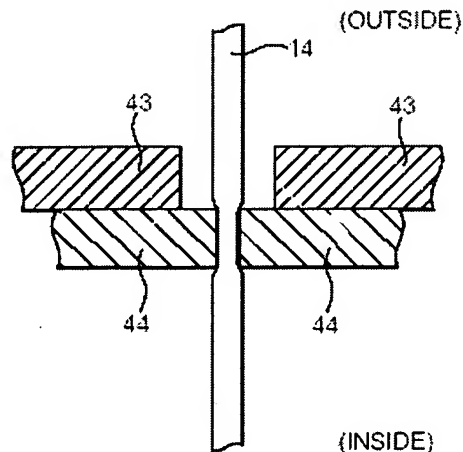
A preferred embodiment of the stylet (46), also referred to in the specification as "catheter stretcher," is illustrated below. Tip (54) on the proximal end of the stylet may be used to make a uniform hole of a precise diameter in the dura.



The hole in the dura may be made by means for applying electrical current to the tip of the stylet to cauterize the dura.

The hemispherical tip of the stylet has a diameter approximately equal to the diameter of the hole to be made in the dura, namely the first predetermined diameter. Further, the diameter of the hole in the dura is not greater than the diameter of the tip of the stylet.

The distal end (48) may be inserted into the lumen of the catheter and, preferably, stretched along the majority of the length of the stylet. Stretched the diameter of the catheter is preferably smaller than the diameter of the hole made in the dura. Once inserted, the stylet is withdrawn from the lumen of the catheter and, preferably, the diameter of the catheter expands to a diameter greater than the diameter of the hole in the dura. This results in the cross-section illustrated below showing the catheter snugly and fully filling the hole made in the dura minimizing leakage of CSF through the hole in the dura.



Having the ability to create a hole of a predetermined diameter related to the diameter of the catheter prevents having a hole of an irregular shape and/or uncontrolled size. The irregular shape and uncontrolled size of the hole in the dura contributes to the leakage of CSF and possible

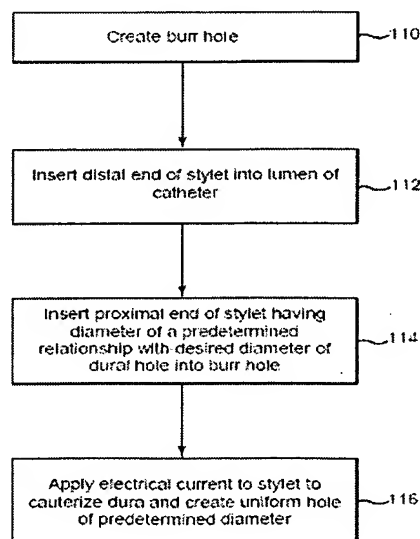
resulting complications. A dura hole of a predetermined size and uniformly round shape allows the catheter to fit snugly in the hole preventing a substantial void allowing CSF leakage and enabling the dura to heal around the catheter sealing the penetration against further leakage.

The invention is easy to use and provides important time savings in use by the surgeon. Minimizing surgical time provides important safety benefits for the patient.

The only “means plus function” language utilized in claim 1 is means for applying an electrical current. This means applies generally to any of many well known electrical cauterization means and refers to the description in paragraph [61] of the specification.

Claim 9

Claim 9 recites a method of making a hole in a dura of a patient having a cranium for the insertion of a catheter. A burr hole is created in the cranium of the patient, if necessary. A stylet is inserted into the lumen of a catheter with a distal end of the stylet formed with a hemispherical tip having a diameter approximately equal to the hole to be established in the dura. The hole in the dura is not greater than the diameter of tip of the stylet. An electrical current is applied to the stylet in order to cauterize the dura creating a hole in the dura approximately equal to the diameter of the tip. The proximal end of the catheter is inserted into the burr hole of the cranium.



No “means plus function” elements are contained in claim 9.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1 and 6 – 8 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 6,761,718, Madsen et al (“Madsen et al ‘718”), in an Office Action made final mailed May 3, 2005 and affirmed in an Advisory Action mailed July 22, 2005

GROUPING OF CLAIMS

The claims are grouped as follows:

Group I: **Claim 1;**

Group II: **Claim 6;**

Group III: **Claim 7; and**

Group IV: **Claim 8.**

.Claim 1 is independent. Claims 6 – 8 depend from claim 1.

Claims 9 and 13 – 15 have been indicated as being allowable and, hence, do not form a part of this appeal.

ARGUMENTS OF APPELLANTS

Madsen '718

Madsen '718 discloses a bipolar coagulator which can be passed through the internal lumen of a ventricular catheter previously implanted into a cranial ventricle of a living subject and engaged in-situ. The bipolar coagulator will provide bipolar electrical arc currents for coagulation cauterization of adherent brain tissues, such as the choroids plexus, which occludes fluid flow into the intake drainage holes in the implanted ventricular catheter.

The bipolar coagulator has a proximal end adapted to be inserted through the lumen of an already inserted ventricular catheter. The bipolar coagulator has two electrodes intended to coagulate adherent brain tissues, such as the choroids plexus, which otherwise would occlude ports in the sidewall of the catheter. Thus, the sole intended purpose of the bipolar coagulator is to clear ports in an already-inserted in-vivo ventricular catheter.

Claim 1

Claim 1 requires an “apparatus for making a hole ... in a dura of a patient for the insertion of a catheter.” In contrast, Madsen '718 discloses a bipolar coagulator for coagulating brain tissue, not for making a hole in the dura, in a catheter already inserted in-vivo, not for the insertion of a catheter. Not only does Madsen '718 not disclose an apparatus for making a hole in the dura, the apparatus disclosed in Madsen '718 is not suitable for making a hole in the dura. The electrodes of the bipolar coagulator disclosed in Madsen '718 are located along the side of the proximal portion of the elongated body in order to match with the ports located on the sides of the catheter. So positioned, the electrodes could not effectively make a hole in the dura. Thus, the bipolar coagulator disclosed in Madsen '718 fails to anticipate claim 1 for this reason alone.

In addition, claim 1 explicitly requires a stylet with a tip having a hemispherical shape and requires specific structural relationships between the elements, namely that the diameter of the hemispherical shape of the tip of the stylet be approximately equal the first predetermined diameter (hole in the dura) and that the first predetermined diameter is not greater than the second predetermined diameter (diameter of the catheter).

These specific structural relationships are not shown nor suggested in the disclosure of Madsen '718. Nor does Madsen '718 achieve the significant advantages associated with these structural elements, namely the control of leakage of CSF around a catheter placed through the dura in order to accomplish shunting into the ventricles and/or into the sagittal sinus. Controlling leakage of CSF can improve shunt performance by controlling or eliminating the potential for the serious side effects.

Not only is claim 1 not anticipated by Madsen '718, there is no disclosure in Madsen '718 to teach or suggest the claimed structure. Thus, Madsen et al also fails to render claim 1 unpatentable for obviousness.

Thus, claim 1 is believed patentable over Madsen '718, the rejection of claim 1 is respectfully believed to erroneous and the Examiner should be reversed in this appeal.

Claim 6

Claim 6 is dependent upon claim 1.

Since claim 1 should be allowable over Madsen '718 and since claim 6 contains each and every limitation of claim 1, then claim 6 should also be allowable over Madsen '718.

Further, claim 6 further requires that the diameter of the hole in the dura be approximately equal to the diameter of the catheter.

Madsen '718 contains no disclosure or suggestion about any relationship between the diameter of the hole in the dura and the diameter of the catheter. Madsen '718 certainly does not show nor suggest that these diameters be approximately equal.

Nor does Madsen '718 achieve the significant advantages associated with these structural elements, namely the control of leakage of CSF around a catheter placed through the dura in order to accomplish shunting into the ventricles and/or into the sagittal sinus. Controlling leakage of CSF can improve shunt performance by controlling or eliminating the potential for the serious side effects.

Not only is claim 6 not anticipated by Madsen '718, there is no disclosure in Madsen '718 to teach or suggest the claimed structure. Thus, Madsen et al also fails to render claim 6 unpatentable for obviousness.

Thus, claim 6 is believed patentable over Madsen '718, the rejection of claim 6 is respectfully believed to erroneous and the Examiner should be reversed in this appeal.

Claim 7

Claim 7 is dependent upon claim 1.

Since claim 1 should be allowable over Madsen '718 and since claim 7 contains each and every limitation of claim 1, then claim 7 should also be allowable over Madsen '718.

Further, claim 7 further requires that the diameter of the hole in the dura be smaller than the diameter of the catheter.

Madsen '718 contains no disclosure or suggestion about any relationship between the diameter of the hole in the dura and the diameter of the catheter. Madsen '718 certainly does not show nor suggest that the diameter of the hole in the dura be smaller than the diameter of the catheter.

Nor does Madsen '718 achieve the significant advantages associated with these structural elements, namely the control of leakage of CSF around a catheter placed through the dura in order to accomplish shunting into the ventricles and/or into the sagittal sinus. Controlling leakage of CSF can improve shunt performance by controlling or eliminating the potential for the serious side effects.

Not only is claim 7 not anticipated by Madsen '718, there is no disclosure in Madsen '718 to teach or suggest the claimed structure. Thus, Madsen et al also fails to render claim 7 unpatentable for obviousness.

Thus, claim 7 is believed patentable over Madsen '718, the rejection of claim 7 is respectfully believed to erroneous and the Examiner should be reversed in this appeal.

Claim 8

Claim 8 is dependent upon claim 7 which is dependent upon claim 1.

Since claims 1 and 7 should be allowable over Madsen '718 and since claim 8 contains each and every limitation of claims 1 and 7, then claim 8 should also be allowable over Madsen '718.

Further, claim 8 further requires that the diameter of the hole in the dura be approximately fifteen percent (15%) smaller than the diameter of the catheter.

Madsen '718 contains no disclosure or suggestion about any relationship between the diameter of the hole in the dura and the diameter of the catheter. Madsen '718 certainly does not show nor suggest that the diameter of the hole in the dura be approximately fifteen percent (15%) smaller than the diameter of the catheter.

Nor does Madsen '718 achieve the significant advantages associated with these structural elements, namely the control of leakage of CSF around a catheter placed through the dura in order to accomplish shunting into the ventricles and/or into the sagittal sinus. Controlling leakage of CSF can improve shunt performance by controlling or eliminating the potential for the serious side effects.

Not only is claim 8 not anticipated by Madsen '718, there is no disclosure in Madsen '718 to teach or suggest the claimed structure. Thus, Madsen et al also fails to render claim 8 unpatentable for obviousness.

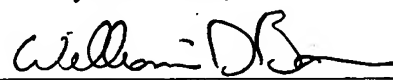
Thus, claim 8 is believed patentable over Madsen '718, the rejection of claim 8 is respectfully believed to erroneous and the Examiner should be reversed in this appeal.

Summary

In view of the arguments presented, the rejection of claims 1 and 6 - 8 as being anticipated by U.S. Patent No. 6,761,718, Madsen et al, should be reversed.

Registration Number 28,052	Telephone Number 612-331-7405
Date February 22, 2006	

Respectfully submitted,

By 
William D. Bauer

APPENDIXLISTING OF CLAIMS

1. An apparatus for making a hole of a first predetermined diameter in a dura of a patient for the insertion of a catheter having a second predetermined diameter, comprising:
 - a catheter having a lumen;
 - a stylet having a first end adapted for insertion in said lumen;
 - said stylet having a second end formed with a tip having a hemispherical shape with a diameter approximately equal to said first predetermined diameter; and
 - means for applying an electrical current to said tip of said stylet to cauterize said dura;wherein said first predetermined diameter is not greater than said second predetermined diameter.
2. – 5. (canceled)
6. An apparatus as in claim 1 wherein said first predetermined diameter is approximately equal to said second predetermined diameter.
7. An apparatus as in claim 1 wherein said first predetermined diameter is smaller than said second predetermined diameter.
8. An apparatus as in claim 7 wherein said first predetermined diameter is approximately fifteen percent (15%) percent smaller than said second diameter.
9. A method of making a hole of a first predetermined diameter in a dura of a patient having a cranium for the insertion of a catheter having a second predetermined diameter, comprising the steps of:
 - determining whether to create a burr hole in said cranium of said patient;
 - inserting a first end of said stylet with a tip having a hemispherical shape with a diameter approximately equal to said first predetermined diameter into said burr hole of said

cranium, wherein said first predetermined diameter is not greater than said second predetermined diameter;

applying an electrical current to said stylet in order to cauterize said dura creating a hole in said dura approximately equal to said diameter of said tip; and

inserting a second end of said stylet into a lumen of a catheter with said second end of said stylet proximal to a distal end of said catheter.

10. – 12. (canceled)

13. A method as in claim 9 wherein said first predetermined diameter is approximately equal to said second predetermined diameter.

14. A method as in claim 9 wherein said first predetermined diameter is smaller than said second predetermined diameter.

15. A method as in claim 14 wherein said first predetermined diameter is approximately fifteen percent (15%) smaller than said second diameter.